

Corrected Exhibit B



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

November 6, 2020

SENT BY EMAIL

Kristin Graham Koehler (kkoehler@sidley.com)
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Sidley Austin LLP 1501 K St., N.W.
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RE: Third Party Subpoena, Notice Under Fed. R. Civ. P. 30(b)(6),
and *Touhy* Request to the Department of Defense in
U.S. ex rel. Simpson v. Bayer et al., Case No. 08-5758 (D. Minn.)

Dear Counsel:

The Defense Health Agency (“DHA”), a component of the U.S. Department of Defense (“DoD”), administers the TRICARE Program and is responding on behalf of DoD to a Subpoena to Testify at a Deposition in a Civil Action, accompanying Notice of Deposition pursuant to Rule 30(b)(6), and request for testimony pursuant to *Touhy v. Ragen*, 340 U.S. 462 (1951), dated October 8, 2020 (collectively “subpoena”). The subpoena was addressed to DoD Office of General Counsel on October 8, 2020, but a courtesy copy was not provided to me, Department of Justice, Senior Trial Counsel Sanjay Bhambhani, or AUSA Ann Bildtsen despite correspondence about your prior Rule 30(b)(6) Notice and your prior Rule 45 subpoena for documents. I did not receive the new Rule 30(b)(6) subpoena until October 28, 2020. I understand that this new subpoena replaces your prior Rule 30(b)(6) subpoena with 12 topics dated August 28, 2020, and that you are withdrawing that subpoena.

As explained in detail below, under DoD’s *Touhy* regulations, the subpoena is unduly burdensome or otherwise inappropriate under the applicable court rules. *See* 32 C.F.R. § 97.6(b)(1). Furthermore, consistent with the protections afforded under Rule 45(d)(1) and (3), this letter further serves as DoD’s written objections to Bayer’s subpoena. We reserve the right to supplement our written objections upon further evaluation of this request and in response to a revised and properly constituted *Touhy* request.

A party seeking the third-party discovery from the United States must comply with the applicable agency’s *Touhy* regulations. *See Touhy*, 340 U.S. at 468-70 (upholding regulation prohibiting agency employees from releasing documents without consent of agency head); 32 C.F.R. § 97.6 (outlining the appropriate procedures that must be followed when testimony is requested from DoD). DHA OGC is authorized under the DoD *Touhy* regulations to determine whether the request or demand complies with DoD’s *Touhy* regulations. *See* 32 C.F.R. § 97.6;

DoD Directive 5405.02, Section 6.2.1.

A subpoena does not circumvent the federal administrative process described above. *Alltel Communications, LLC v. DeJordy*, 675 F.3d 1100, 1103-1104 (8th Cir. 2012) (explaining that sovereign immunity is a defense to a third party subpoena issued to a federal agency; an agency's response to a proper *Touhy* request must be reviewed under the Administrative Procedure Act); *Charges of Unprofessional Conduct Against 99-37 v. Stuart*, 249 F.3d 821, 825 (8th Cir. 2001) ("Sovereign immunity protects a federal officer from being compelled to testify when instructed not to do so by her department.").

Based on our review, your subpoena appears to be overbroad and unduly burdensome to DoD, a non-party to this action, under the applicable court rules. *See* 32 C.F.R. § 97.6(b)(1). The subpoena identifies four broad topics without sufficient particularity and covers a period over 20 years old, from January 1, 1998 to through February 28, 2002. It is our understanding that this period exceeds the relevant time-period of this litigation, which is limited to a seven-month period from January 2001 to August 2001, when Baycol was withdrawn from the market. Because your demand for testimony covers a period far exceeding the relevant time period for the underlying litigation, it remains overbroad, unduly burdensome, and disproportional to the needs and scope of the case under 32 C.F.R. § 97.6(b)(1) and Fed. R. Civ. P. 26(b)(1).

Many of the identified topics also lack sufficient specificity or relevance as they seek testimony that appears unrelated to the renewal contract remaining at issue in the underlying litigation. Furthermore, many of the topics seek testimony that Bayer already possesses or should possess. As you know, the DoD has already produced to you nearly 700 pages of documents over the course of the past months. The testimony sought appears to be "unreasonably cumulative, or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive." Fed. R. Civ. P. 26(b)(2)(C)(i). Furthermore, given the breadth, scope, and time-frame of the identified topics, you have not complied with your duty under Fed. R. Civ. P. 45(d)(1), which provides that "[a] party or attorney responsible for issuing a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena." If you would like to discuss narrowing the topics to the issues remaining in the case, please let us know.

Beyond these issues, and to preserve our objections, set forth below are DoD's additional written objections to the subpoena pursuant to Fed. R. Civ. P. 45. Because our review of the subpoena continues, we reserve the right to supplement these objections in the future. We also specifically reserve and does not waive other objections that may be applicable in discovery or at trial.

First, DoD objects to your use of the following terms as vague, ambiguous, overbroad, and unduly burdensome: "information" and "relied on" (Topic No. 1), "experience," "LDL-C reduction capabilities," "cost savings," "medical risk," "monotherapy," and "combination" (Topic No. 2), "policies and practices," "relating to DoD's payment of claims," "Zocor (simvastatin)," "any non-formulary statin," "denied any claim for payment," "basis," "allegedly failed to disclose," and "risks of rhabdomyolysis" (Topic No. 3), and "hold notice," "issued," "document retention," "efforts," "preserve," and "evidence" (Topic No. 4).

Second, DoD objects to Topic No. 1 as applied to the “award of the Original Contract” because it is our understanding that the “Original Contract” is no longer at issue in the underlying litigation. Furthermore, as discussed above, DoD objects to Topics Nos. 2 and 3 because they are overbroad, unduly burdensome, cover an unreasonable time-frame, and fail to describe with reasonable particularity the matters for examination, making it difficult if not impossible to designate an appropriate official who may testify as to the particular topic or topics. For example, Topic 3 seeks information about “whether DoD ever denied any claim for payment on the basis that Bayer allegedly failed to disclose risks of rhabdomyolysis” without regard to timeframe. DoD further objects on the grounds that this particular topic as well as the others (1) have no relevance to Bayer’s defenses at issue in the litigation, (2) are disproportional to the needs of the case, (3) pertain to events that occurred almost 20 years ago and involve personnel who are no longer employed at DoD, and (4) would require unduly burdensome research and reconstruction of dated events.

Third, DoD objects to the subpoena as it fails to allow a reasonable time to comply given receipt was not until October 28, 2020. *See* Fed. R. Civ. P. 45(d)(3)(A)(i). The subpoena identifies overbroad and unduly burdensome topics, many of which concern events that took place almost twenty years ago, many of which are irrelevant and disproportional to the needs of the case.

Fourth, DoD objects to the subpoena as it seeks disclosure of privileged or other protected information. *See* Fed. R. Civ. P. 45(d)(3)(A)(iii).

Fifth, DoD objects to the subpoena as it imposes an undue burden as a result of the breadth, scope, and timeframe of the topics listed for examination. *See* Fed. R. Civ. P. 45(d)(3)(A)(iv).

Sixth, DoD objects to the subpoena as Bayer has failed to comply with its duty “to avoid imposing undue burden or expense on a person subject to the subpoena.” Fed. R. Civ. P. 45(d)(1).

Seventh, in your letter with your latest subpoena, you identify the persons who may have knowledge of the topics in which you are interested because they appear to have been involved (e.g., Contracting Officer McKeown, Fred Beal). After 20 years, these persons are no longer with the DoD. The DoD is not obligated to identify a person to testify on information that is no longer known or reasonably available to the organization.

Based on the reasons set forth above, we object to the subpoena and require a proper *Touhy* request consistent with DoD’s *Touhy* regulations to initiate the approval process. We are, however, working to identify a person or persons who could testify on topics narrowed from the ones in your subpoena, if anyone remains in DoD with that knowledge. We will not be able to do so by November 19, 2020, the date you specify for the deposition. If you have any questions or concerns or would like to discuss the *Touhy* requirements further, please contact me at (303) 676-3705.

Sincerely,

Mark A. Jacobs
Attorney Advisor

cc:

Sanjay M. Bhambhani, Senior Trial Counsel, DOJ Fraud Section, Civil Division

Ann Bildtsen, AUSA, District of Minnesota

Song Kim, DHA OGC

Andrew Good, DLA OGC

Katherine McCullough, DLA OGC

J.M. Carrion, DLA OGC



DEFENSE HEALTH AGENCY
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September 15, 2020

SENT BY EMAIL

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Josh Fougere (jfougere@sidley.com)
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Dear Counsel:

The Defense Health Agency (“DHA”), a component of the U.S. Department of Defense (“DoD”), administers the TRICARE Program and is responding on behalf of DoD to a Subpoena to Testify at a Deposition in a Civil Action, accompanying Notice of Deposition pursuant to Rule 30(b)(6), and request for testimony pursuant to *Touhy v. Ragen*, 340 U.S. 462 (1951), dated August 28, 2020 (collectively “subpoena”). The subpoena was received on September 1, 2020 and commands DoD to designate one or more persons to appear for a deposition on September 23, 2020, at your offices in Washington, D.C., to testify on behalf of DoD on twelve separate topics. As explained in detail below, under DoD’s *Touhy* regulations, the testimony commanded under the subpoena cannot be authorized because the subpoena is unduly burdensome or otherwise inappropriate under the applicable court rules. *See* 32 C.F.R. § 97.6(b)(1). Furthermore, consistent with the protections afforded under Rule 45(d)(1) and (3), this letter further serves as DoD’s written objections to Bayer’s subpoena. We reserve the right to supplement our written objections upon further evaluation of this request and in response to a revised and properly constituted *Touhy* request.

A party seeking the third party discovery from the United States must comply with the applicable agency’s *Touhy* regulations. *See Touhy*, 340 U.S. at 468-70 (upholding regulation prohibiting agency employees from releasing documents without consent of agency head); 32 C.F.R. § 97.6 (outlining the appropriate procedures that must be followed when testimony is requested from DoD). DHA OGC is authorized under the DoD *Touhy* regulations to determine whether the request or demand complies with DoD’s *Touhy* regulations. *See* 32 C.F.R. § 97.6; DoD Directive 5405.02, Section 6.2.1.

A subpoena does not circumvent the federal administrative process described above. *Alltel Communications, LLC v. DeJordy*, 675 F.3d 1100, 1103-1104 (8th Cir. 2012) (explaining that sovereign immunity is a defense to a third party subpoena issued to a federal agency; an agency’s

response to a proper *Touhy* request must be reviewed under the Administrative Procedure Act); *Charges of Unprofessional Conduct Against 99-37 v. Stuart*, 249 F.3d 821, 825 (8th Cir. 2001) (“Sovereign immunity protects a federal officer from being compelled to testify when instructed not to do so by her department.”).

Based on our review, your subpoena is unduly burdensome to DoD, a non-party to this action, and otherwise inappropriate under the applicable court rules. *See* 32 C.F.R. § 97.6(b)(1). The subpoena identifies twelve overbroad and unduly burdensome topics that lack sufficient particularity and that cover a twenty-three year period, from January 1, 1998 to the present. It is our understanding that this twenty-three year period far exceeds the relevant time period remaining in this litigation, which is limited to a seven-month period from January 2001 to August 2001, when Baycol was withdrawn from the market. Therefore, your demand for testimony covering a twenty-three year period, far exceeding the relevant time period for the underlying litigation, is overbroad, unduly burdensome, and disproportional to the scope of the case under 32 C.F.R. § 97.6(b)(1) and Fed. R. Civ. P. 26(b)(1).

Many of the identified topics also lack sufficient specificity or relevance as they seek testimony that appears unrelated to the renewal contract remaining at issue in the underlying litigation. Furthermore, many of the topics seek testimony that Bayer already possesses or should possess. As you know, the DoD has already produced to you nearly 700 pages of documents over the course of the past months. The testimony sought appears to be “unreasonably cumulative, or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive.” Fed. R. Civ. P. 26(b)(2)(C)(i). Finally, given the breadth, scope, and time-frame of the identified topics, you have not complied with your duty under Fed. R. Civ. P. 45(d)(1), which states that “[a] party or attorney responsible for issuing a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena.” If you would like to discuss narrowing your request to the information necessary to the issues remaining in the case, please let us know.

Beyond these issues, and to preserve our objections, set forth below are DHA’s additional written objections to the subpoena pursuant to Fed. R. Civ. P. 45. Because DHA’s review of the subpoena continues, DHA reserves the right to supplement these objections in the future. DHA also specifically reserves and does not waive other objections that may be applicable in discovery or at trial.

First, DHA objects to your definition of “DEPARTMENT OF DEFENSE or DoD” as vague, ambiguous, overbroad, and unduly burdensome to the extent it does not differentiate between the Military Health System, the TRICARE Basic Program, and other DoD components. (Schedule A, Definition and Instructions ¶ 5, Topic Nos. (1-12).

Second, DHA objects to your use of the following terms as vague, ambiguous, overbroad, and unduly burdensome: “factors and information” (Topic Nos. 1-3), “knowledge of the risk” (Topic No. 4), “any discussions with Bayer on this topic” (Topic Nos. 4, 5), “knowledge of the class risk” (Topic No. 5), “in combination with any statin” (Topic No. 5), “clinical experience” (Topic No. 7), “any hospitals or physicians” (Topic No. 7), “any drug purchased” (Topic No. 10), “the same type of contract” (Topic No. 10), “based on allegations” (Topic No. 11), “the underlying contract” (Topic No. 11), “medical risks associated with the drug” (Topic No. 11), “participation or knowledge” (Topic No. 12).

Third, as discussed above, DHA objects to the twelve topics because they are overbroad, unduly burdensome, cover an unreasonable time-frame (January 1, 1998 through the present), and fail to describe with reasonable particularity the matters for examination, making it difficult if not impossible to designate an appropriate official who may testify as to the particular topic or topics. DHA further objects on the grounds that several of the topics: (1) have no relevance to Bayer's claims or defenses remaining at issue in the litigation, (2) are disproportional to the needs of the case, (3) pertain to events that occurred almost 20 years ago and involve personnel who are no longer employed at DoD, and (4) would require unduly burdensome research and reconstruction of dated events.

Fourth, DHA objects to the subpoena as it fails to allow a reasonable time to comply. *See* Fed. R. Civ. P. 45(d)(3)(A)(i). The subpoena identifies 12 overbroad and unduly burdensome topics, many of which concern events that took place almost twenty years ago, many of which are irrelevant and disproportional to the needs of the case, directing that DoD be prepared to testify by September 23, 2020. The subpoena fails to allow DoD a reasonable time to comply.

Fifth, DHA objects to the subpoena as it seeks disclosure of privileged or other protected information. *See* Fed. R. Civ. P. 45(d)(3)(A)(iii).

Sixth, DHA objects to the subpoena as it imposes an undue burden as a result of the breadth, scope, and timeframe of the topics listed for examination. *See* Fed. R. Civ. P. 45(d)(3)(A)(iv).

Seventh, DHA objects to the subpoena as Bayer has failed to comply with its duty "to avoid imposing undue burden or expense on a person subject to the subpoena." Fed. R. Civ. P. 45(d)(1).

Based on the reasons set forth above, we object to the subpoena and require a proper *Touhy* request consistent with DoD's *Touhy* regulations to initiate the approval process. If you decide to submit a *Touhy* request, your request should comply with DOD *Touhy* regulations. To assist us in evaluating any *Touhy* request, your request should include an explanation of the nature of the case, identify specifically what material matters are in dispute in the case, identify what specific information is sought from DOD, and explain how that requested information is material and relevant to any disputed issue in the case. Your request should also explain why the information sought cannot be obtained from another source (such as from the opposing party), or by less burdensome means, such as through the release of documents instead of through testimony.

If you have any questions or concerns or would like to discuss the *Touhy* requirements further, please contact me at (303) 676-3705.

Sincerely,

A handwritten signature in blue ink that reads "Mark A. Jacobs". The signature is written in a cursive, slightly slanted style.

Mark A. Jacobs
Attorney Advisor

cc:

Sanjay M. Bhambhani, Senior Trial Counsel, DOJ Fraud Section, Civil Division

Ann Bildtsen, AUSA, District of Minnesota

Song Kim, DHA OGC

Daniel K. Poling, Defense Logistics Agency OGC